

REMARKS/ARGUMENTS

This response is timely filed with 2 months of mailing of the Office Action made Final from the US Patent Office. **Expedited review is respectfully requested.**

Claims 1-3 and 18 are withdrawn.

Claims 4-17 are canceled.

New claims 19-31 are pending.

New claims 19-31 are presented for consideration. No new subject matter has been added. Claims 19-31 are based on canceled claims 4-17 and withdrawn claim 18. Applicant's attorney had spoken with Examiner Winston in a related application and has incorporated some of the suggestions of Examiner Winston into the pending claims. Applicant thanks Examiner Winston's consideration in these matters.

Cancellation of claims 4-17 is not an acquiescence to the pending rejections. Cancellation of claims 4-17 is done to expedite the prosecution of the pending application. In view of the discussions with Examiner Winston, it was reasonable to assume that submission new claims 19-31 would expedite prosecution. Canceled claims 4-17 may be pursued in this or a continuation application.

Rejection of Claims 4-6, 12, 15 and 16 under 35 U.S.C. § 103(a)

Claims 4-6, 12, 15 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US Patent No. 6,485,760, hereinafter "Matsuyama") in view of Hoffman (The Complete Illustrated Herbal, *Practical Herbalism, The Preparation of Herbs*, 1996, pages 20-33, hereinafter "Hoffman"). Applicants respectfully traverse this rejection for at least the following reasons.

Claims 4-6, 12, 15 and 16 have been canceled, thereby obviating the basis of the rejection.

Newly presented claims 19-31 pertain to soft gel capsules that are prepared by a process. The process by which the soft gel capsule is prepared includes the steps of heating rice bran oil to about 35° C in a container, adding a filler, adding Corosolic acid, continuously stirring the mixture, and encapsulating the mixture in the soft gel capsule.

Matsuyama discloses an oral composition, a hard “tablet” (See column 5, line 50 through column 6, line 20) with a powdered herbal extract containing Corosolic acid. As the Office Action of September 9, 2003 notes, Matsuyama fails to teach or suggest in any of its disclosure that anything but a tablet could be used with the Corosolic acid. Furthermore, Matsuyama fails to provide any motivation or an expectation of success that a Corosolic concentrate could be formulated into anything but a tablet.

Hoffman fails to remedy the deficiencies of Matsuyama. Hoffman, is a general teaching that dried herbs can be placed into a two-piece gelatin capsule. As Hoffman shows at page 26, these are gelatin capsules that come in two pieces. The powdered herbs must be placed into the two halves. One half of the capsule has a larger circumference than the second one half of the capsule. The two halves are pushed together with the larger half sliding over the smaller half, to form a seal and the two-piece capsule. As a consequence, *the herbs are present in the capsule as a powdered dry composition.*

In stark contrast, the present invention provides a soft gel capsule that encapsulates a flowable liquid that contains Corosolic acid liquefied in rice bran oil.

Hoffman fails to teach or suggest, provide any motivation or an expectation of success such that one having ordinary skill in the art would prepare a soft gel capsule by heating rice bran oil to about 35° C in a container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Consequently, neither Matsuyama or Hoffman, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 4-17 under 35 U.S.C. § 103(a)

Claims 4-17 as previously amended stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama in view of Hoffman, US Patent No. 6,303,586 (hereinafter "McPeak et al."), US Patent No. 6,407,068 (hereinafter "LaGrone"), US Patent No. 5,552,427 (hereinafter "Matsutani et al.") and US Patent No. 5,980,902 (hereinafter "Shanmuyasundam et al."). Applicants respectfully traverse the rejection for at least the following reasons.

Claims 4-17 have been canceled, thereby obviating the basis of the rejection.

Matsuyama and Hoffman have been discussed in the previous section. The arguments presented therein are reiterated and incorporated here in their entirety.

McPeak et al. disclose stabilized rice bran derivatives that are provided to an individual in a variety of forms, such as by simply sprinkling the derivative on another food substance (i.e., salad, bread, cereal, etc.) being a major ingredient in a multigrain ready to eat cereal, incorporating it into a baked product (breads, muffins, waffles, etc), pasta, healthy dessert and snacks (athletic bar, healthy drink, etc.) and high fiber foods (See Column 6, lines 19 through 24).

McPeak et al. fail to remedy the deficiencies of Matsuyama or Hoffman, alone or in combination. McPeak et al. fail to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art the preparation of a soft gel capsule with any rice bran derivative. Moreover, McPeak et al. fail to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art the preparation of a soft gel capsule with Corosolic acid. Additionally, McPeak et al. fail to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a

container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

LaGrone fails to remedy the deficiencies of Matsuyama, Hoffman and McPeak et al., alone or in combination.

LaGrone teaches the use of silica to prevent diabetes.

LaGrone does not teach or suggest the use of silica in a soft gel capsule. Furthermore, LaGrone does not teach or suggest the use of silica in combination with Corosolic acid in a soft gel capsule.

LaGrone fails to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler such as silica, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

Matsutani et al. disclose that *tablets* can be *polished* with bees wax to *coat* the tablet.

Matsutani et al. do not teach or suggest the use of bees wax *within* a soft gel capsule. Furthermore, Matsutani et al. do not teach or suggest the use of bees wax in combination with Corosolic acid in a soft gel capsule.

Matsutani et al. fail to remedy the deficiencies of Matsuyama, Hoffman, McPeak et al., and LaGrone, alone or in combination.

Matsutani et al. *coat* the *tablet* with bee's wax. In contrast, the presently claimed subject matter incorporates the bee's wax within a *soft gel capsule*.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler, such as bee's wax, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, and encapsulating the mixture into a soft gel capsule, such that the bee's wax is contained *inside* the soft gel capsule.

Reconsideration and withdrawal of this basis of rejection is respectfully requested.

Shanmuyasundam et al. disclose an extract of *Gymnema sylvestre*.

Shanmuyasundam et al. do not teach or suggest the use of *Gymnema sylvestre* in a soft gel capsule. Shanmuyasundam et al. do not teach or suggest the use of *Gymnema sylvestre* in combination with Corosolic acid in a soft gel capsule.

Shanmuyasundam et al. fail to remedy the deficiencies of Matsuyama, Hoffman, McPeak et al., LaGrone and Matsutani et al. alone or in combination.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a soft gel capsule containing Corosolic acid could be prepared by heating rice bran oil to about 35° C in a container, adding a filler, adding a herb, i.e., Corosolic acid, continuously stirring the resultant mixture, adding *Gymnema sylvestre* and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of this rejection is respectfully requested.

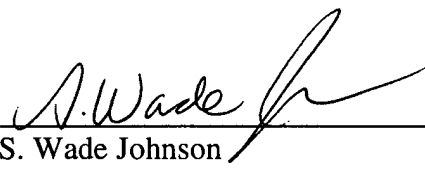
Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested. If a telephonic consultation would help to expedite the processing of the application, the Examiner is urged to contact the attorney below at the Examiner's convenience.

Respectfully submitted,

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